REMARKS

Entry of the foregoing, re-examination and reconsideration of the subject matter identified in caption, as amended, pursuant to and consistent with 37 C.F.R. §1.111, and in light of the remarks which follow, are respectfully requested.

The specification has been amended to correct a typographical error, by replacing "3 × 16 10^{-5}%" in paragraphs [0054] and [0060] with --3.16 x 10^{-5}%--. These amendments are supported by the specification, for example, paragraphs [0074], [0077] and [0078], Examples 2 and 3, and claim 9. The specification has also been amended to delete "(http://pubs.acs.org/hotartcl/tcaw/00/may/dong.html)" in paragraph [0060]. In addition, the specification has been amended to insert a Brief Description of the Drawings section. This amendment is supported by the specification, for example, paragraphs [0099], [0101], [0103], [0106] and [0115].

Claims 1, 3, 28, 33 and 37 have been amended to incorporate the partial subject matter of claim 26. Claims 16 and 53 have been rewritten in independent form and also amended to incorporate the partial subject matter of claim 26. Claim 17 has been amended in accordance with the amendments to claim 16. Claims 2, 3 and 28 have been amended to further improve its form, which do not narrow the scope of the claims. Claims 26 and 55 have been canceled.

Upon entry of the Amendment, claims 1-25, 27-54 and 56-67 will be all the claims pending in the application.

I. Response to Objection to the Specification

The specification is objected to for informalities as set forth in paragraph 10 of the Office Action.

Applicants respectfully submit that the specification as amended herein does not contain informalities. As noted above, Applicants have amended the specification to delete the hyperlink and insert a Brief Description of the Drawings section. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the objection.

II. Response to Rejection under 35 U.S.C. § 112, First Paragraph

Claims 1-38, 41-44 and 47-63 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth at pages 5-8 of the Office Action.

Applicants respectfully submit that the present claims are in compliance with the requirements under 35 U.S.C. § 112 for at least the following reasons.

The written description requirement under 35 U.S.C. § 112, first paragraph requires that the disclosure describes the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429,1438 (Fed. Cir. 2003).

It is asserted that "[t]he claims do not require that the stimulants possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature" (page 6, lines 7-9 of the Office Action).

Applicants respectfully disagree. It should be noted that all the claims recite "a peripheral nervous system stimulant," which by itself calls for a particular biological activity.

Further, claim 13 recites that "the peripheral nervous system stimulant is an agent which induces a sensorial response linked to the deployment of sensitive skin nerves." Moreover, claim 14 recites that "the peripheral nervous system stimulant is a substance that can induce an unattractive sensation when applied topically to the skin and can induce release

of at least one of substance P and CGRP when applied topically to the skin." These recitations clearly describe the specific biological activity and distinctive features of the peripheral nervous system stimulant.

Additionally, various claims further define the peripheral nervous system stimulant as specific compounds. For instance, claim 15 recites that the peripheral nervous system stimulant is a natural capsaicinoid, a synthetic capsaicinoid, a lactic acid, a glycolic acid, an ethanol at a concentration greater than 50%, or a mustard oil. Claim 16 recites that the peripheral nervous system stimulant is selected from the group consisting of a capsaicin, a homocapsaicin, a homodihydrocapsaicin, and a nordihydrocapsaicin. Claims 17 and 20 recite that the peripheral nervous system stimulant is capsaicin. Claim 37 recites that a stimulant is a capsaicinoid or a mustard oil. Claim 52 recites that the peripheral nervous system stimulant is a natural capsaicinoid, a synthetic capsaicinoid, a synthetic extract or a plant extract. Claim 53 recites that the capsaicinoid is a capsaicin, a homocapsaicin, a homodihydrocapsaicin, a nordihydrocapsaicin, or a dihydrocapsaicin. Claim 54 recites that the capsaicinoid is a capsaicin. These specific compounds have particular structures.

It is further asserted that "the specification does not teach a relationship between the structure and function of the genus of peripheral nervous stimulants, cosmetics, vehicles and unattractive sensations encompassed by the claimed methods" (page 6, lines 2-4 from the bottom of the Office Action).

Applicants wish to submit the following comments.

First, as noted above, Applicants have amended the claims to specifically recite that the unattractive sensation is at least one selected from the group consisting of stinging, pins and needles, itching, pruritus, hotness and pulling.

Further, the specification provides specific examples, in particular, Examples 9 and 10, to demonstrate that application of a capsaicin solution and a lactic acid solution followed by a capsaicin solution can cause an unattractive sensation. Therefore, one skilled in the art may reasonably conclude that at least a homocapsaicin, a homodihydrocapsaicin, a nordihydrocapsaicin, and a dihydrocapsaicin, which are structurally closely related to capsaicin, would have the same or similar functions as capsaicin.

Turning to the term "vehicle," this term is commonly used in the art, as evidenced by, e.g., U.S. Patent No. 6,139,850 to Hahn et al., which is cited by the Examiner (see, claim 1). Therefore, one skilled in the art may reasonably conclude that physiologically acceptable vehicles provide the same or similar results. Moreover, claims 20-25, 37, 38 and 48-51 are limited to an aqueous solution and/or an aqueous-alcoholic solution. An aqueous-alcoholic solution is exemplified in the specification, e.g., in Examples 9 and 10.

Furthermore, the term "cosmetic" is defined in paragraph [0071] of the specification by reference to Cosmetic Directive 76/768/EEC.

Based on the above-mentioned descriptions, Applicants submit that the specification provides sufficient description of the present invention to one skilled in the art.

III. Response to Rejections under 35 U.S.C. § 103(a)

Claims 1-17, 20-27, 28-38, 41-44 and 48-55 are rejected under 35 U.S.C. § 103(a) as being obvious over Robinson et al., *Contact Dermatitis*, "Evaluation of a quantitative clinical method for assessment of sensory skin irritation," 45:205-213, 2001, for the reasons set forth at pages 9-12 of the Office Action. In addition, claims 56-63 are rejected under 35 U.S.C. § 103(a) as being obvious over Robinson et al. and further in view of U.S. Patent No. 6,139,850 to Hahn et al. for the reasons set forth at pages 12-13 of the Office Action.

Applicants respectfully traverse the rejections for the following reasons.

One objective of the present invention is to further increase the diversity of models and devices available to the public for evaluating the skin sensitivity of an individual and provide a test allowing the determination of a sensitive skin population. Applicants advise that the studies regarding sensitive skin have shown that the threshold of sensitivity of the skin was very low, less than 1.10 - 3%.

Specifically, the present invention is directed to a non-therapeutic method of evaluating the level of skin neurosensitivity of an individual or identifying persons having sensitive skin by using a composition containing a peripheral nervous system stimulant in an amount of between 1×10^{-6} and 1×10^{-4}% by weight, relative to the total weight of the composition. This concentration of the peripheral nervous system stimulant is critical because when using more concentrated solutions, the test may lead to false positive results (i.e., an individual who feels unpleasant sensation without having sensitive skin).

Robinson et al. aims to the development of "better methods for predictive testing and risk assessment" of dermatological products and standard tests for the evaluation of irritant potential of new ingredients or products. In the study procedure employed in Robinson et al., intensities of self-assessed sensations and of experimental application of chemicals are compared. According to Robinson et al., there is no clear pattern of answers or correlation between these answers and cutaneous reaction of tested individuals.

As noted by the Examiner, in Robinson et al., 100-10,000 μM capsaicin in 80% ethanol was used. Robinson et al. does not suggest that capsaicin at a low concentration, such as 1×10^{-6} and 1×10^{-4}% by weight, relative to the total weight of the composition as recited in the present claims, would be useful for cosmetic diagnosis allowing identification

of subjects with sensitive skin from others, without any pain and without giving rise to adverse side effects.

Hahn et al. is relied upon as disclosing facial irritation trials using 10% benzoyl peroxide wash product and thus does not rectify the deficiencies of Robinson et al.

In view of the foregoing, Applicants respectfully submit that the present claims are not obvious over Robinson et al., alone or in combination with Hahn et al., and thus the rejections should be withdrawn.

IV. Conclusion

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order and such action is earnestly solicited. If there are any questions concerning this paper or the application in general, the Examiner is invited to telephone the undersigned at (202) 452-7932 at his earliest convenience.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

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By: _____
Fang Liu, Ph.D.
Registration No. 51,283